UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
1:12-cv-1020

HEART IMAGING TECHNOLOGIES, LLC, Plaintiff, v. MERGE HEALTHCARE INCORPORATED, Defendant.	)	**DECLARATION OF GEORGE SHIH, M.D., M.S.**

GEORGE SHIH declares as follows:

INTRODUCTION

1. I am an adult; I reside in New York City. I am a physician and I am a board-certified radiologist. Since 2006, I have been employed by Weill Cornell Medical Center ("Weill Cornell") in New York City. A copy of my curriculum vitae, containing an accurate and current description of my education, work experience and publications, is attached as **Exhibit 1**. In brief, I received my medical degree from Duke University School of Medicine in May 2000, a master's degree in Electrical Engineering from Duke University School of Engineering in January 1997, and a bachelor's degree in Computer Science from Duke University in 1994. I have been an Assistant Professor of Radiology at Weill Cornell Medical Center since 2006, an Adjunct Assistant Professor of Radiology at Columbia University Medical Center since 2010, and Vice Chairman

for Informatics at Weill Cornell Medical Center's Department of Radiology since 2012.

2. As Vice Chairman for Informatics at the Department of Radiology, I am very involved in the decision making process involving the procurement of medical image and information management systems. As part of such work, I have become familiar with the needs of physicians at Weill Cornell and other hospitals for medical imaging management systems, including systems whereby physicians can view medical images electronically on devices located at Weill Cornell as well as via web browsers, smart phones, laptop devices, and other devices. I am also familiar with trends in the industry and the legal regulations affecting the healthcare industry, including the trends and regulations pertaining to electronic health records and "Meaningful Use." I am additionally generally familiar with various medical image management systems, including Merge Health Care Incorporated's ("Merge's") iConnect and Honeycomb systems discussed below.

3. I have been asked by Merge to give certain opinions and comments with respect to issues related to Heart Imaging Technology's (HIT's) Motion for a preliminary injunction in the above lawsuit. My educational background and experiences qualify me to give opinions and comments in this case and on the below matters.

MATERIALS AND INFORMATION REVIEWED

4. In forming my opinions as stated herein on the validity of the asserted patent claims identified above, I considered the following:

a. HIT's U.S. Patent No. 8,166,381 (" '381 Patent").

b. HIT's Motion for Preliminary Injunction of December 27, 2012.

c. The references discussed below.

5. Unless otherwise indicated, all of my opinions and comments set forth below are based on my experience and qualifications described in paragraph 2 above and on the materials and information described in paragraph 4 above, and all of my opinions are expressed to a reasonable degree of engineering certainty.

6. It is my understanding that this lawsuit is at a very early stage, that only limited information relevant to the case is available to Merge and to me, and that additional relevant information is likely to be discovered and may be provided to me as the lawsuit progresses. Accordingly, I reserve the right to amend and supplement the opinions and comments set forth below as the lawsuit progresses.

THE '381 PATENT

7. Claim 1 of the '381 Patent reads as follows. I have numbered the alleged "six elements" of Claim 1 (as characterized by HIT) using bracketed numbers, although I believe this is an over-simplification of Claim 1:

> [1] A method of managing medical information, comprising:
> receiving at a first computer a plurality of image series resulting from a patient medical imaging procedure, each image series comprising one or

more digital medical images in a format that is incompatible with displaying in an Internet web browser;

[2] providing a pointer associated with the patient medical imaging procedure;

[3] in response to user selection of the pointer at a second computer,

providing an Internet web page for display in an Internet web browser on the second computer, the Internet web page forming a user interface for a medical image workstation when displayed in the Internet web browser without requiring software executing outside the Internet web browser on the second computer, the user interface comprising a rectangular grid of one or more rows and one or more columns for simultaneously displaying a plurality of navigational images in the user interface of the Internet web page, and

[4] providing to the user the plurality of navigational images for display in the user interface of the Internet web page, the plurality of navigational images corresponding to different ones of the image series from the patient medical imaging procedure, the plurality of navigational images comprising a format that is compatible for displaying in an Internet web browser without requiring software executing outside the Internet web browser on the second computer, the plurality of navigational images being converted to a browser compatible format before being transmitted over the Internet; and

[5] in response to user selection of one of the plurality of navigational images, providing to the user the one or more digital medical images of the image series associated with the selected one of the navigational images for display in the user interface of the Internet web page, the one or more digital medical images comprising a format that is compatible for displaying in the Internet web browser without requiring software executing outside the Internet web browser on the second computer, the one or more digital medical images providing medical information to the user, the one or more digital medical images being converted to a browser compatible format before being transmitted to the second computer,

[6] wherein the medical image workstation enables user navigation among the plurality of navigational images and the one or more digital medical images of the image series to permit medical diagnosis from the one or more digital medical images without requiring software executing outside the Internet web browser.

CLAIM 1 OF THE '381 PATENT INCLUDES VAGUE AND/OR AMBIGUOUS TERMS

8. As has been explained to me, the property right protected by a patent is defined by the claims of the patent, which appear as numbered paragraphs at the end of the text. Thus, the first step in analyzing either the infringement or validity of a patent claim begins with an analysis of the claim itself to "interpret" its terms, also referred to as "claim construction."

9. HIT alleges that the "Accused Products clearly infringe Claim 1 of the '381 patent based on the plain language of the claim." (See HIT's Motion at III.A.2.) However, many of the terms used in Claim 1 of the '381 patent do not have a plain meaning.

10. For example, Claim 1 states "…*the Internet web page forming a user interface for a medical image workstation when displayed in the Internet web browser without requiring software executing outside the Internet web browser*."

11. Initially, the meaning of "without requiring software executing outside the Internet web browser" is vague and ambiguous. For example, it is not apparent whether this phrase allows for software that is executed by or within the Internet web browser (such as plug-ins that function inside the Internet web browser), or excludes all software other than the Internet web browser. If this phrase allows for some software as long as the software is executed inside the Internet web browser, then HIT's position that Claim 1 of the '381 patent is directed to viewers that are "zero-download" or "zero-footprint" is unsupportable.

12. Additionally, the term "software" can have different meanings. On the one hand, software can be used to very broadly mean "a collection of computer programs and related data that provides the instructions for telling a computer what to do and how to do it. Software refers to one or more computer programs and data held in the storage of the computer. In other words, software is a set of programs, procedures, algorithms and its documentation concerned with the operation of a data processing system" (**Exhibit 2**).[1] On the other hand, the term software can be used more narrowly to refer to, for example, system software (**Exhibit 3**),[2] or application software (**Exhibit 4**).[3] It is therefore unknown what software is not required in Claim 1 as a result of the statement "without requiring software executing outside the Internet web browser." Claim 1 could be providing the specified functionality, for example, "without requiring [system] software executing outside the Internet web browser," "without requiring [application] software executing outside the Internet web browser," or "without requiring [any code or algorithm] executing outside the Internet web browser." What is meant by terms such as "software" as used in Claim 1 impacts the scope of Claim 1 for the infringement and invalidity analyses.

[1] See, e.g., "Software" at http://en.wikipedia.org/wiki/Software (last accessed January 21, 2012).

[2] See, e.g., "System software" at http://en.wikipedia.org/wiki/System_software (last accessed January 21, 2013) ("System software (or systems software) is computer software or an operating system designed to operate and control the computer hardware and to provide a platform for running application software").

[3] See, e.g., "Application software" at http://en.wikipedia.org/wiki/Application_software (last accessed January 21, 2013) ("Application software, also known as an application or an app, is computer software designed to help the user to perform specific tasks. Examples include enterprise software, accounting software, office suites, graphics software and media players.").

13. Further, based on the structure of the phrase "…the Internet web page forming a user interface for a medical image workstation when displayed in the Internet web browser without requiring software executing outside the Internet web browser" of Claim 1, it is not clear, for example, whether it is the Internet web page that is displayed, or whether it is the user interface that is formed, "without requiring software executing outside the Internet web browser." Similarly, the phrase "wherein the medical image workstation enables user navigation among the plurality of navigational images and the one or more digital medical images of the image series to permit medical diagnosis from the one or more digital medical images without requiring software executing outside the Internet web browser" of Claim 1 is structured such that it is not clear, for example, whether "the medical image workstation enables user navigation," or whether the medical diagnosis is permitted, without requiring software executing outside the Internet web browser."

14. Claim 1 also includes the phrase "format that is incompatible with displaying in an Internet web browser." This phrase does not have a plain meaning because compatibility of a file format with an application is highly dependent on the specific application, the operating system under which it operates, its version, and its features. There are dozens of browsers that are now or that have been available to consumers for use with different operating systems

(**Exhibits 5-7**).[4] These browsers can vary greatly in their capabilities, each having different strengths and weaknesses. For example, the PNG file format cannot be opened using earlier versions of Netscape Navigator (**Exhibit 8**),[5] while this format can be opened using Internet Explorer. As another example, the TIFF file format can be opened using Internet Explorer and Safari, but not using Google Chrome.[6]

15. Such ambiguities undermine the position taken in HIT's Motion that Claim 1 has a plain meaning, and that the Accused Products are infringing as a result of the plain meaning of Claim 1.

THE '381 PATENT IS NOT INFRINGED

16. As has been explained to me, a patent claim is infringed when the accused product includes every limitation exactly as recited in the claim (as properly construed). For example, if a claim recites the limitations of A, B and C, the accused product infringes the claim if it includes A, B and C. On the other hand, a product having elements A, B and D, where D differs from C, would not literally infringe.

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[4] See, e.g., "List of web browsers" at http://en.wikipedia.org/wiki/List_of_web_browsers (last accessed January 21, 2013) (**Exhibit 5**); http://www.webdevelopersnotes.com/design/browsers_list.php3 (last accessed January 21, 2013) (**Exhibit 6**). See also "Timeline of web browsers" at http://upload.wikimedia.org/wikipedia/commons/7/74/Timeline_of_web_browsers.svg (last accessed January 21, 2013) (**Exhibit 7**).

[5] See, e.g., Comparison of web browsers, Image format support, at http://en.wikipedia.org/wiki/Comparison_of_web_browsers#Image_format_support (last accessed January 21, 2013).

[6] See id. (**Exhibit 8**).

17. Among other reasons, Claim 1 of the '381 Patent is not infringed because none of the Accused Products contains the claim element "*wherein the medical image workstation enables user navigation among the plurality of navigational images and the one or more digital medical images of the image series to permit medical diagnosis from the one or more digital medical images without requiring software executing outside the Internet web browser*."

18. HIT's expert, Dr. Grizzard, takes the conclusory position that "[t]he Merge product satisfies this element because it gives users navigational images and full image series in browser-compatible formats over the Internet." (See Grizzard Decl. ¶13.) However, this ignores the requirement of Claim 1 that no software executing outside the Internet web browser can be required. This is in part because this clause of Claim 1 does not specify on what machine the not-required software is executed. That is, "without requiring software executing outside the Internet web browser" suggests that no software executing outside the Internet web browser *on any computer* is required.

19. Nonetheless, if we presume that "without requiring software executing outside the Internet web browser" means "using only the browser," as Dr. Grizzard contends (D.E. No. 16-1, p. 4), then "the sixth element" of Claim 1 requires that "…the medical image workstation enables user navigation among the plurality of navigational images and the one or more digital medical images of the image series to permit medical diagnosis from the one or more digital medical

images [*using only the Internet web browser*]" based on Dr. Grizzard's Declaration.

20. That is, Claim 1 thus requires that "user navigation among the plurality of navigational images and the one or more digital medical images of the image series" must be performed without "any additional software" (D.E. No. 16, p. 12) other than the Internet web browser. As already suggested, unlike other elements of Claim 1, the sixth element does not limit "without requiring software executing outside the Internet web browser" to "on the second computer."

21. As I understand it, the Accused Products provide users with "thumbnails," each thumbnail representing a series of one or more images. Selection of a thumbnail displays one larger-sized image from the corresponding series of images. The user is able to "navigate" the image workstation by scrolling through the images in the series of images being displayed, or by selecting a different thumbnail. Because only one image from the series is retrieved from a server at a time, scrolling among images in a series or selecting a different thumbnail requires the server to transmit a new image to the user's computer to replace the image already being displayed. That is, assuming for the sake of argument that the thumbnails and full-sized images of the Accused Products correspond to the "navigational images" and "digital medical images" of Claim 1, respectively, then "user navigation" (by switching between selected thumbnails or by scrolling through the images in a corresponding series of images) requires software other than the Internet web browser, such as software on a web server.

Other software required is software that controls an input/output device (such as a mouse) and software that that is used to translate DICOM images into a common image format (such as PNG). Because software executing outside the Internet web browser is required by the Accused Products for the alleged medical image workstation to enable user navigation among the plurality of navigational images and the one or more digital medical images of the image series to permit medical diagnosis from the one or more digital medical images," "the sixth element" of Claim 1 is not satisfied, and the Accused Products cannot be said to be infringing Claim 1 of the '381 patent.

22. Because all elements of Claim 1 must be satisfied in the Accused Product for there to be potential infringement, the Accused Products cannot be said to be infringing because they do not satisfy at least these requirements.

CLAIM 1 OF THE '381 PATENT IS INVALID BECAUSE IT IS ANTICIPATED BY *SAKUSABE ET AL.* (EXHIBIT 9)[7]

23. According to HIT's expert, Dr. Grizzard, Claim 1 of '381 patent can be divided into six elements (see Grizzard Decl. ¶6). Accepting Dr. Grizzard's apparent interpretation of the claims as allegedly capturing the purported features of the Accused Products, each of these six elements is taught by *Sakusabe et al*. It is my opinion that Claim 1 of the '381 patent is consequently invalid because of the *Sakusabe et al.* reference.

[7] Takaya Sakusabe, Michio Kimura, & Yuzo Onogi; "On-demand server-side image processing for web-based DICOM image display," Proc. SPIE 3976, Medical Imaging 2000: Image Display and Visualization, 359 (April 18, 2000); doi:10.1117/12.383060; http://dx.doi.org/10.1117/12.383060.

24. The *Sakusabe et al*. reference was not considered by the USPTO when examining the patent application that culminated in the '381 patent. In my opinion, the USPTO would not have considered Claim 1 to be innovative had it known about this reference.

25. *Sakusabe* et *al.* teaches that "[t]he implementation of an imaging workstation in our architecture shows that Web based image display could have the look and feel of an imaging workstation" (see pg. 364).

26. This article was published at least as far back as April 18, 2000, and resulted from a February 12, 2000 conference.[8] February 2000 is well before the '381 patent's filing date of September 29, 2005, and years before the alleged 2004 timeframe that "Heart IT invented its zero-footprint viewer technology" (see Judd Decl. ¶11). It is further likely that the work that culminated in the conference and the publication preceded the conference, and might have been performed in 1999 or before.

27. Each of the "six elements" will now be discussed in relation to the *Sakusabe et al.* article.

> *[1] A method of managing medical information, comprising: receiving at a first computer a plurality of image series resulting from a patient medical imaging procedure, each image series comprising one or more digital medical images in a format that is incompatible with displaying in an Internet web browser;*

[8] See http://proceedings.spiedigitallibrary.org/proceeding.aspx?articleid=922293, citing Conference Volume 3976, Medical Imaging 2000: Image Display and Visualization, Seong K. Mun, San Diego, CA, February 12, 2000 (last accessed January 21, 2013) (**Exhibit 10**).

28. *Sakusabe et al.* teaches that DICOM images are received at a server to be processed (see, e.g., Fig. 1.3, pg. 360). This teaches receiving at a first computer (the server) a plurality of image series resulting from a patient medical imaging procedure (DICOM), each image series comprising one or more digital medical images in a format that is incompatible with displaying in an Internet web browser (the DICOM format is purportedly incompatible with displaying in an Internet web browser).

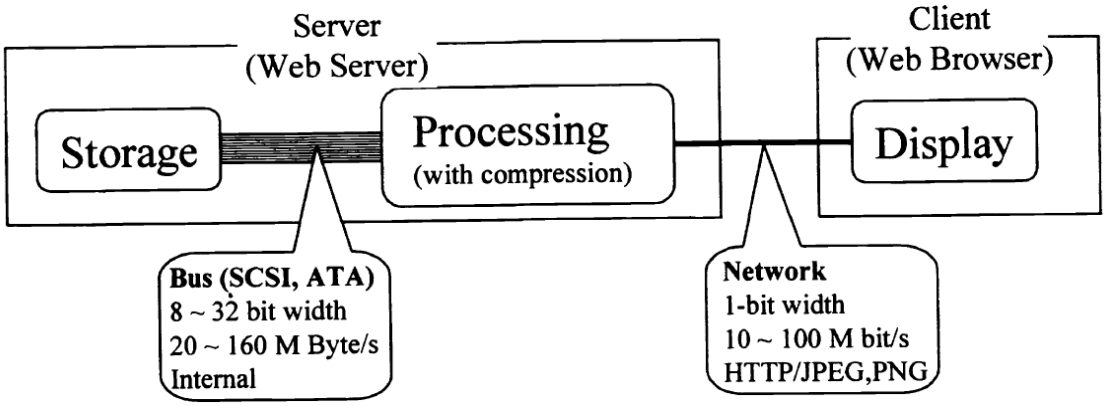

Figure 1-3 of *Sakusabe et al.*

[2] providing a pointer associated with the patient medical imaging procedure;

29. *Sakusabe et al.* teaches that "In our approach, images are processed on server-side when a client requests and delivered to the client immediately" (pg. 360). It also teaches that an HTML document is generated from attributes of DICOM files, which contain information associated with the patient medical imaging procedure (see, e.g., pg. 362). It additionally teaches that a URL that specifies a particular image can be used (such as http://SERVER/scripts/dio-image.isa/DICOM/ct1.dcm provided as an example on pg. 361). Accordingly,

Sakusabe et al. teaches that a pointer is provided, and that the pointer is associated with the patient medical imaging procedure.

> *[3] in response to user selection of the pointer at a second computer, providing an Internet web page for display in an Internet web browser on the second computer, the Internet web page forming a user interface for a medical image workstation when displayed in the Internet web browser without requiring software executing outside the Internet web browser on the second computer, the user interface comprising a rectangular grid of one or more rows and one or more columns for simultaneously displaying a plurality of navigational images in the user interface of the Internet web page, and*

30. *Sakusabe et al.* teaches that user selection of a pointer at user's computer is the "client request" for images. A user interface with a rectangular grid of navigational images is provided (see, e.g., Fig. 2). As taught by *Sakusabe et al.*, a "[u]ser can … navigate with thumbnails…" (pg. 362, emphasis added). One advantage of the system of *Sakusabe et al.* is that "[f]ree or inexpensive Web browsers could be used as client software" (see pg. 361). The system of *Sakusabe et al.* does not require additional software downloads "to process images on client-side" (see pg. 360). Instead, it utilizes "Internet standardized technologies" such as JavaScript (which is executed fully inside the web browser) and image formats such as JPEG and PNG for viewing on the web browser.

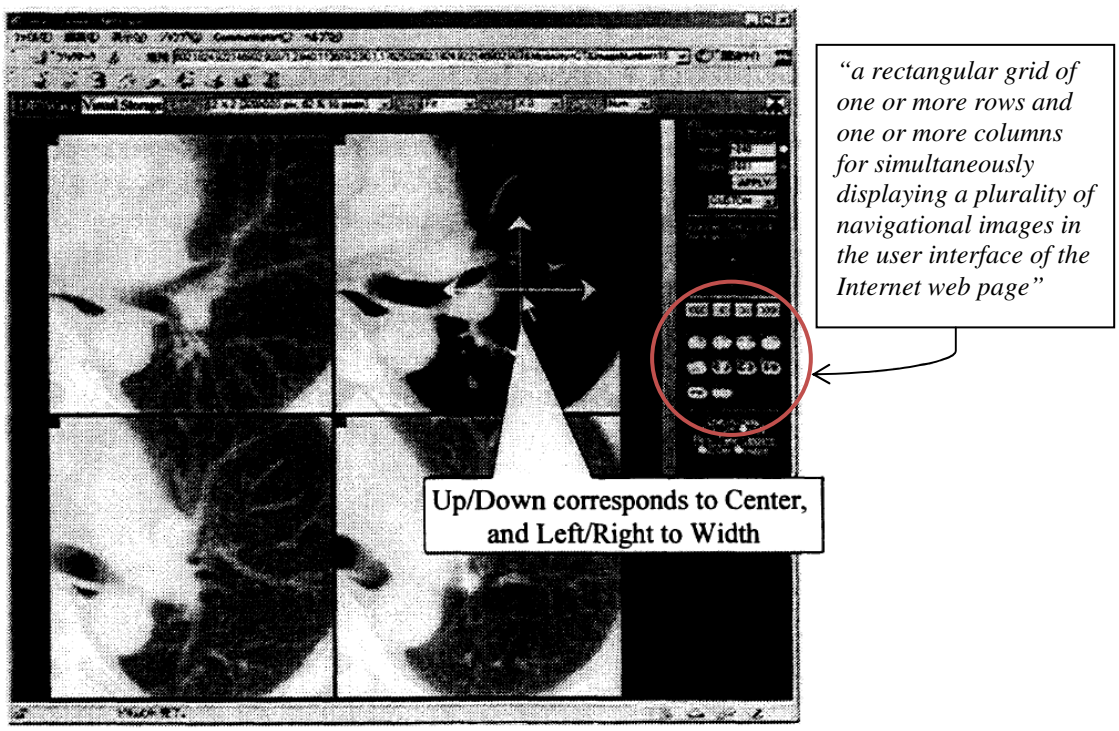

Figure 2 of *Sakusabe et al.*

[4] providing to the user the plurality of navigational images for display in the user interface of the Internet web page, the plurality of navigational images corresponding to different ones of the image series from the patient medical imaging procedure, the plurality of navigational images comprising a format that is compatible for displaying in an Internet web browser without requiring software executing outside the Internet web browser on the second computer, the plurality of navigational images being converted to a browser compatible format before being transmitted over the Internet; and

31. *Sakusabe et al.* teaches that user selection of a pointer at user's computer is the "client request" for images. A user interface with a rectangular grid of navigational images is provided (see, e.g., Fig. 2). As taught by *Sakusabe et al.*, a "[u]ser can … navigate with thumbnails…" (pg. 362). One advantage of the system of *Sakusabe et al.* is that "[f]ree or inexpensive Web browsers could be used as client software" (see pg. 361). The system of *Sakusabe et al.* does not

require Java plug-ins "to process images on client-side" (see pg. 360). As shown in Figure 1-3 of *Sakusabe et al.*, image processing is performed on the server-side (web server) and not on the client side (web browser) (see pg. 360).

> *[5] in response to user selection of one of the plurality of navigational images, providing to the user the one or more digital medical images of the image series associated with the selected one of the navigational images for display in the user interface of the Internet web page, the one or more digital medical images comprising a format that is compatible for displaying in the Internet web browser without requiring software executing outside the Internet web browser on the second computer, the one or more digital medical images providing medical information to the user, the one or more digital medical images being converted to a browser compatible format before being transmitted to the second computer,*

32. *Sakusabe et al.* state that they "utilize Internet standard technologies such as HTTP (for image transfer), JPEG (for lossy compression) and PNG (Portable Network Graphics) (for lossless compression)." One advantage of the system of *Sakusabe et al.* is that "[f]ree or inexpensive Web browsers could be used as client software" (see pg. 361). The system of *Sakusabe et al.* does not require Java plug-ins "to process images on client-side" (see pg. 360). As shown in Figure 1-3 of *Sakusabe et al.*, image processing is performed on the server-side (web server) and not on the client side (web browser) (see pg. 360).

> *[6] wherein the medical image workstation enables user navigation among the plurality of navigational images and the one or more digital medical images of the image series to permit medical diagnosis from the one or more digital medical images without requiring software executing outside the Internet web browser.*

33. *Sakusabe et* al. states that "implementation of an imaging workstation in our architecture shows that Web based image display could have

the look and feel of an imaging workstation" (pg. 364). That is, the system of *Sakusabe et al.* emulates a medical image workstation without the need for downloading additional software. Further, *Sakusabe et al.*'s "architecture may be useful for most of clinicians in a hospital, and for a radiologist who is in the situation that he/she could not use high performance imaging workstation" (see pg. 364). That is, the system of *Sakusabe et al.* permits medical diagnosis.

34. As shown in the below graphic, the system architecture of *Sakusabe et al.* corresponds with the system architecture taught by Figure 2 of the '381 patent (reproduced on the left side of the graphic). That is, the architecture for converting DICOM images to a "common" format before transmitting the images to the user's Internet web browser so the user does not require additional software downloads (i.e., so the system is "zero-download" as HIT characterizes the term) is taught by *Sakusabe et al.* In the below graphic, Figure 1-3 of *Sakusabe et al.* is reproduced on the right side, rotated 90 degrees for purposes of illustration.

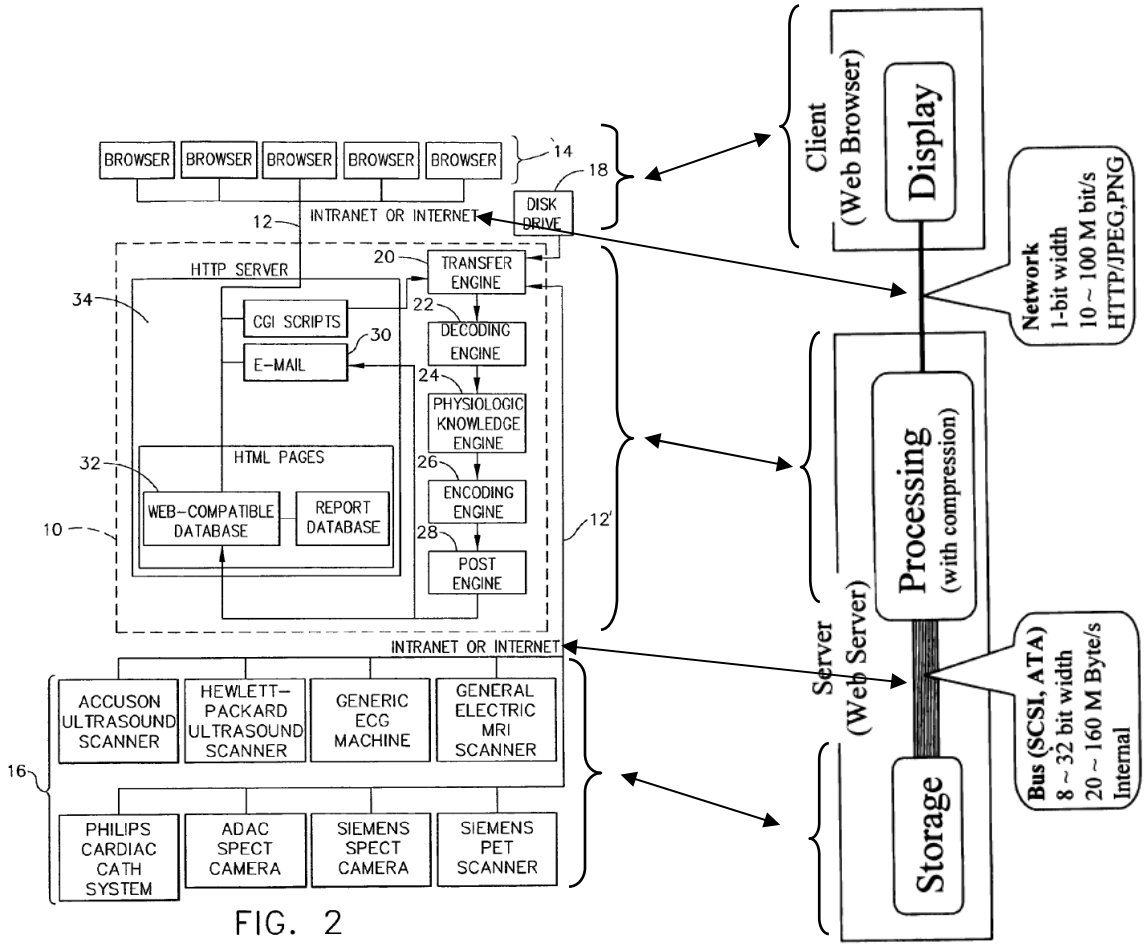

FIG. 2

35. To summarize, it is clear that *Sakusabe et al.* teaches every element of Claim 1 of the '381 patent, and that Claim 1 of the '381 patent is therefore invalid.

CLAIM 1 OF THE '381 PATENT IS INVALID BECAUSE IT IS ANTICIPATED BY *FEINGOLD ET AL.* (EXHIBIT 11)[9]

36. Accepting Dr. Grizzard's apparent interpretation of the claims as allegedly capturing the purported features of the Accused Products, each of the "six elements" (as characterized by Dr. Grizzard) is taught by *Feingold et al.* It is

[9] Eric R. Feingold; George J. Grevera; Reuben S. Mezrich; Steven C. Horii; Satjeet S. Khalsa, et al. "Web-based radiology applications for clinicians and radiologists," Medical Imaging 1997:60-71. SPIE; http://dx.doi.org/10.1117/12.274630.

my opinion that Claim 1 of the '381 patent is consequently invalid because of the *Feingold et al.* reference.

37. The *Feingold et al.* reference was not considered by the USPTO when examining the patent application that culminated in the '381 patent. In my opinion, the USPTO would not have considered Claim 1 to be innovative had it known about this reference.

38. This article was published in 1997, many years before the alleged 2004 timeframe that "Heart IT invented its zero-footprint viewer technology" (see Judd Decl. ¶11).

39. Each of the "six elements" will now be discussed in relation to the *Feingold et al.* article.

> *[1] A method of managing medical information, comprising: receiving at a first computer a plurality of image series resulting from a patient medical imaging procedure, each image series comprising one or more digital medical images in a format that is incompatible with displaying in an Internet web browser;*

40. *Feingold et al.* teaches that DICOM images are received at a web server to be processed (see, e.g., Fig. 2, pg. 62). This teaches receiving at a first computer (the server) a plurality of image series resulting from a patient medical imaging procedure (DICOM), each image series comprising one or more digital medical images in a format that is incompatible with displaying in an Internet web browser (the DICOM format is purportedly incompatible with displaying in an Internet web browser). Figure 2 of *Feingold et al.* is also reproduced below

(upside down) in comparison with the architecture of the '381 patent to illustrate that *Feingold et al.* teaches the system of the '381 patent.

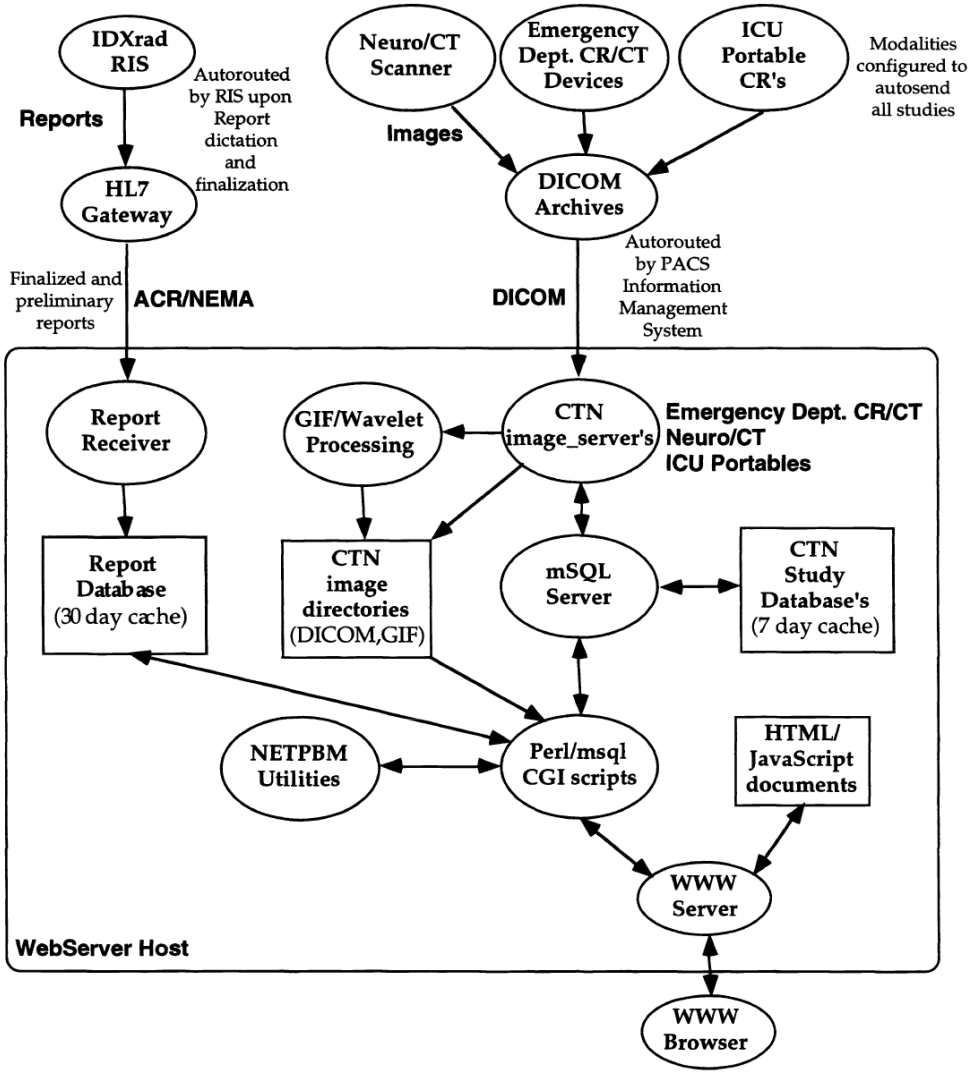

Figure 2 of *Feingold et al.*

[2] providing a pointer associated with the patient medical imaging procedure;

41. *Feingold et al.* provides a report database with studies associated with a patient medical imaging procedure, as shown in Figure 3 (pg. 64):

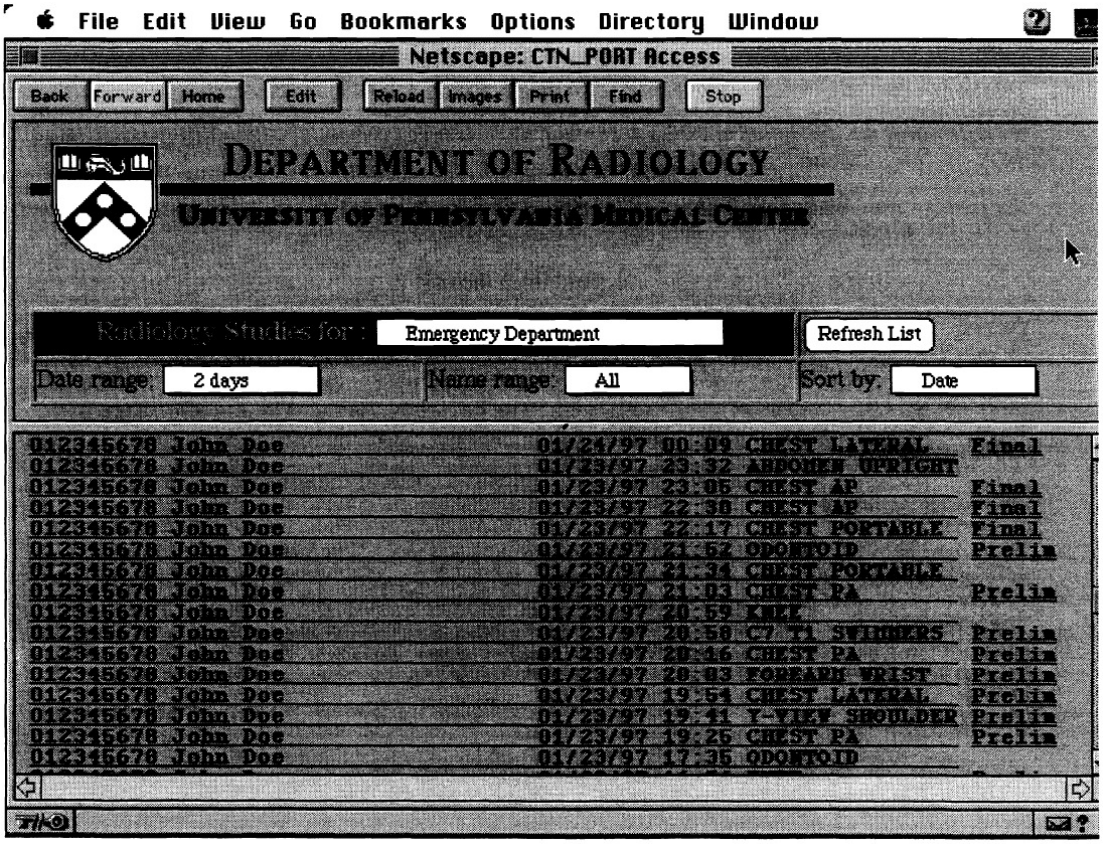

Figure 3 of *Feingold et al.*

42. *Feingold et al.* also teaches that "The function assembles the query parameters into a URL pointing to a Perl CGI that performs the database query which then returns the resulting studies to the bottom frame display." (pg. 65). Accordingly, *Feingold et al.* teaches that a pointer is provided, and that the pointer is associated with the patient medical imaging procedure.

[3] in response to user selection of the pointer at a second computer, providing an Internet web page for display in an Internet web browser on the second computer, the Internet web page forming a user interface for a medical image workstation when displayed in the Internet web browser without requiring software executing outside the Internet web browser on the second computer, the user interface comprising a rectangular grid of one or more rows and one or more columns for simultaneously displaying a plurality of navigational images in the user interface of the Internet web page, and

43. *Feingold* et *al.* teaches that "[o]nce a study is selected, a multi-frame HTML document is loaded" (see pg. 66). A "series frame … is filled with thumbnails of each image in a selected series" (see pg. 66). A user interface with a rectangular grid of navigational images is thus provided (see, e.g., Fig. 4, pg. 65):

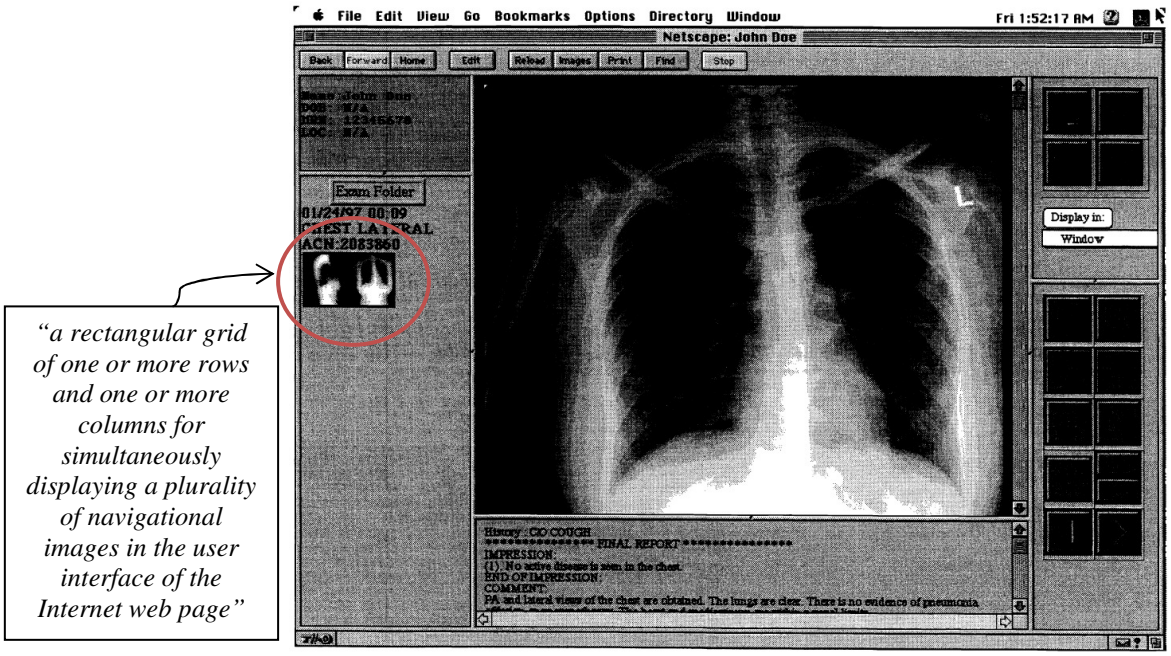

Figure 4 of *Feingold et al.*

44. The system of *Feingold et al.* does not require additional software downloads because it utilizes scripts that are executed fully inside the web browser

and image formats such as GIF for viewing on the web browser. As *Feingold et al.* states, "We have avoided the temptation to use 'plug-ins' to bypass the limitations of HTML and JavaScript." (See pg. 70.)

> *[4] providing to the user the plurality of navigational images for display in the user interface of the Internet web page, the plurality of navigational images corresponding to different ones of the image series from the patient medical imaging procedure, the plurality of navigational images comprising a format that is compatible for displaying in an Internet web browser without requiring software executing outside the Internet web browser on the second computer, the plurality of navigational images being converted to a browser compatible format before being transmitted over the Internet; and*

45. *Feingold et al.* teaches that a study frame on the left of the screen below the Demographics Frame is loaded in reverse chronological order with thumbnail sized images from each study in the patient's folder" (see pg. 66). The browser of *Feingold et al.* does not require additional software because "all images are stored in DICOM and GIF formats" (see pg. 66) and "Netscape 3.x browser supports both GIF and JPEG formats natively" (see pg. 68). *Feingold et al.* states that "We have avoided the temptation to use 'plug-ins' to bypass the limitations of HTML and JavaScript." (See pg. 70.) As shown in Figure 2 (reproduced below) of *Feingold et al.*, image processing is performed on the web server before images are transmitted to the web browser (see pg. 62).

> *[5] in response to user selection of one of the plurality of navigational images, providing to the user the one or more digital medical images of the image series associated with the selected one of the navigational images for display in the user interface of the Internet web page, the one or more digital medical images comprising a format that is compatible for displaying in the Internet web browser without requiring software executing outside the*

Internet web browser on the second computer, the one or more digital medical images providing medical information to the user, the one or more digital medical images being converted to a browser compatible format before being transmitted to the second computer,

46. *Feingold et al.* states that "Selecting a thumbnail image invokes a JavaScript function that loads the full sized image or series into the image frame and the diagnostic *report*, if available, into the report frame." (See pg. 66.) The browser of *Feingold et al.* does not require additional software because "all images are stored in DICOM and GIF formats" (see pg. 66) and "Netscape 3.x browser supports both GIF and JPEG formats natively" (see pg. 68). As shown in Figure 2 (reproduced below) of *Feingold et al.*, image processing is performed on the web server before images are transferred to the web browser (see pg. 62). As *Feingold et al.* states, "We have avoided the temptation to use 'plug-ins' to bypass the limitations of HTML and JavaScript." (See pg. 70.)

[6] wherein the medical image workstation enables user navigation among the plurality of navigational images and the one or more digital medical images of the image series to permit medical diagnosis from the one or more digital medical images without requiring software executing outside the Internet web browser.

47. *Feingold et al.* teaches that a study frame on the left of the screen below the Demographics Frame is loaded in reverse chronological order with thumbnail sized images from each study in the patient's folder" (see pg. 66). *Feingold et al.* states that "Selecting a thumbnail image invokes a JavaScript function that loads the full sized image or series into the image frame and the diagnostic *report*, if available, into the report frame." (See pg. 66.) The browser

of *Feingold et al.* does not require additional software because "all images are stored in DICOM and GIF formats" (see pg. 66) and "Netscape 3.x browser supports both GIF and JPEG formats natively" (see pg. 68). *Feingold et al.* states that "We have avoided the temptation to use 'plug-ins' to bypass the limitations of HTML and JavaScript." (See pg. 70.) As shown in Figure 2 (reproduced below) of *Feingold et al.*, image processing is performed on the web server before images are transmitted to the web browser (see pg. 62).

48. The system of *Feingold et al.* further permits medical diagnosis from the one or more digital medical images, as recited in Claim 1 of the '381 patent. As stated in the Abstract of *Feingold et al.*, "The University of Pennsylvania Radiology Department has developed a suite of Web based applications for clinicians and radiologists to provide wide spread, cost-effective and easy access to all radiological information. The Image Viewer application provides clinicians and radiologists access to all diagnostic reports and digital images performed in the last week…. Image control options [which are typically provided by medical image workstations] including zoom/pan, rotate, flip, and window/level are all available." Consequently, the system of *Feingold et al.* emulates a medical image workstation that permits medical diagnosis.

49. As shown in the below graphic, the system architecture of *Feingold et al.* corresponds with the system architecture taught by Figure 2 of the '381 patent (reproduced on the left side of the graphic). That is, the architecture for converting DICOM images to a "common" format before transmitting the images

to the user's Internet web browser so the user does not require additional software downloads (i.e., so the system is "zero-download" as HIT characterizes the term) is taught by *Feingold et al.* It is noted that Figure 2 of *Feingold et al.* (on the right side of the below graphic) is rotated 180 degrees for purposes of illustration only, and that this does not change the analysis.

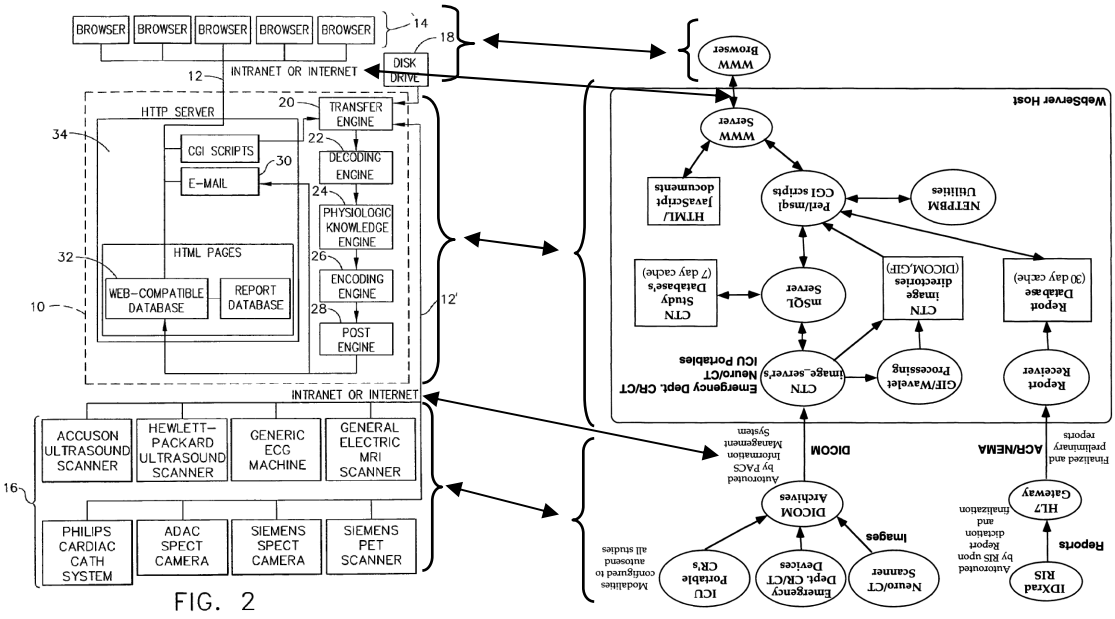

FIG. 2

50. To summarize, it is clear that *Feingold et al.* teaches every element of Claim 1 of the '381 patent, and that Claim 1 of the '381 patent is therefore invalid.

CLAIM 1 OF THE '381 PATENT IS OBVIOUS IN VIEW OF ONE OR MORE OF THE REFERENCES CITED IN THIS DECLARATION, AND EACH OF THE ALLEGEDLY INNOVATIVE FEATURES OF CLAIM 1 OF THE '381 PATENT WAS WELL KNOWN PRIOR TO THE TIME OF INVENTION

51. The prior art teaches each element of Claim 1, and it would have been obvious to combine the teachings of the prior art to make the method of

Claim 1. Claim 1 of the '381 patent is obvious in view of the prior art and thus invalid.

52. For example, conversion of DICOM images into JPEG/GIF/JPEG before sending to a browser was well-known. See, e.g., *Sakusabe et al.* (discussed above), *Feingold et al.*, (discussed above), and *Zhang et al.* (**Exhibit 12**).[10]

53. As shown in the below graphic, the system architecture of *Zhang et al.* corresponds with the system architecture taught by the '381 patent. That is, the architecture for converting DICOM images to a "common" format before transmitting the images to the user's Internet web browser so the user does not require additional software downloads (i.e., so the system is "zero-download" as HIT characterizes the term) is taught by *Zhang et al.* (See *Zhang et al.* Fig. 4, reproduced below in comparison with Fig. 2 of the '381 patent).

[10] Zhang J., Sun, J., & Stahl, J, PACS and Web-based image distribution and display, *Computerized Medical Imaging and Graphics* 27 (2003) 197–206.

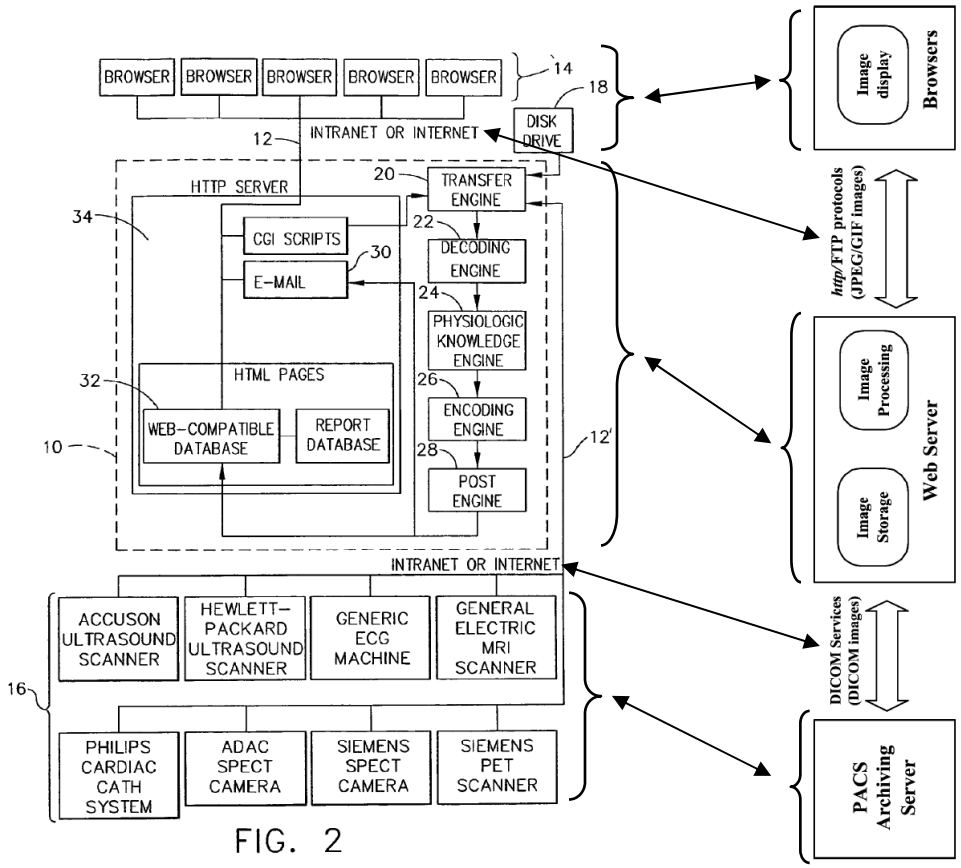

FIG. 2

54. Emulation of workstation using Internet web browsers is taught by, e.g., *Sakusabe et al.* (discussed above). See, e.g., *Sakusabe et al.* Fig. 2.

55. "Zero-download" medical image viewing (as HIT characterizes the term) using computing devices has been available at least since 1997. See, e.g., *Sakusabe et al.* and *Feingold et al.* (both discussed above). See also, e.g., "Live Picture Launches Flagship Enterprise Image Servers" (**Exhibit 13**)[11] and "OphthWeb---cost-effective telemedicine for ophthalmology." (**Exhibit 14**)[12]

[11] www.thefreelibrary.com/Live+Picture+Launches+Flagship+Enterprise+Image+Servers-a020893397 ("The new Enterprise Editions give Web and enterprise users controlled viewing of remarkably detailed Zoom(TM) images in real time over any network without the need for Web browser plug-ins. Designed for enterprise applications including online commerce, image asset management, medical imaging, and defense and intelligence applications, Live Picture Image Servers already have amassed widespread industry and customer support. … Live Picture's patent-pending Universal Viewing lets users examine and zoom into multi-resolution Flashpix(TM) images without the need for client

56. Conversion of DICOM images to such formats as JPEG and PNG was performed years before the filing date of the '381 patent. See, e.g.:

a. DeJarnete, Wayne T., Web technology and its relevance to PACS and teleradiology (**Exhibit 15**).[13]

b. U.S. Patent No. 5,986,662 ("The images of the output in this embodiment are converted to PNG format for correct viewing within a web browser. Posting to an Internet web server provides instant access to authorized associates of the user, such as the referring physician of the patient. See col. 29, ll. 23-35.) (**Exhibit 16**).

57. Conversion of DICOM images to other formats and presentation of the converted images as thumbnails has been around since at least 1996. See, e.g., *Thomsen et al.*, A World Wide Web Based Access to Clinical Patient Data"

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software or plug-ins, and it works with standard Web browsers. Universal Viewing even works in non-traditional PC environments such as Web TV, network appliances, and Windows CE devices.") (last accessed January 21, 2013).

[12] http://www.hkmj.org/article_pdfs/hkm9809p300.pdf ("'OphthWeb' is an ophthalmic electronic medical record that can be accessed locally and globally via the Internet. … OphthWeb can provide telemedicine and electronic medical records at low cost and great convenience. … OphthWeb provides a user-friendly interface to the WWW for both doctors and patients. All image formats are integrated into the network and can be viewed readily by any WWW-browser software.") (last accessed January 21, 2013).

[13] See http://www.appliedradiology.com/Issues/2000/08/Articles/Web-technology-and-its-relevance-to-PACS-and-teleradiology.aspx ("In its simplest form, a Web server-based teleradiology system works as follows: 1) Images are received from imaging systems in the radiology department (generally by means of DICOM). 2) The received images are converted into a standard image format, such as JPEG or TIFF, and stored on the server. The demographic data associated with an image is stripped out and placed in its own text file. The image file and the text file are associated with each other by means of a computer directory structure, or database. 3) A remote user connects to the server, over the Internet, using a general purpose Web browser without any additional software. 4) The user is presented with a list (directory) of viewable images by means of a Web page formatted in HTML and transferred to the remote user over the Internet, using HTTP. 5) Upon selecting an image to view, the user causes the Web server to build a Web page that contains the requested image and the information from the associated demographic text file. This Web page is transferred to the remote user over the Internet, using HTTP.") (last accessed January 21, 2013).

(**Exhibit 17**) at page 362 ("small GIF icons which show minimized view of the original ACR/NEMA images").

58. A person skilled in the art would have been motivated to combine the teachings of the prior art references to achieve a method of managing medical information. The skilled person would have reasonably expected to succeed in his or her efforts.

NO IRREPARABLE HARM

59. In his Declaration, Dr. Judd states that only 35% of US hospitals have adopted Electronic Health Records (see Judd Decl. Ex. 1). Although this may be true, the large majority of hospitals have already adopted PACS. According to "Picture Archiving and Communication Systems: A 2000-2008 Study (**Exhibit 18**),[14] in 2008, 92.2% percent of hospitals with over 250 beds had PACS installed and 98.5% percent of hospitals with over 500 beds had PACS installed. Those numbers are expected to be even higher today.

60. Most of the popular PACS vendors which have the largest market share offer web viewers. These viewers are typically included in a hospital PACS installation; therefore, the vast majority of hospitals in the United States likely already have a web-based medical image viewer integrated with their PACS system. Some of these web viewers are "zero-download" and others may require a plug-in such as ActiveX. For example, at my institution we have the GE

[14] See http://www.himss.org/foundation/docs/PACS_ResearchWhitePaperFinal.pdf (last accessed January 21, 2013).

WebPACS product which requires an ActiveX plug-in and works with Internet Explorer which is still the most commonly used web browser today.

61. I believe Dr. Grizzard's assessment of the expense of using a web viewer that requires a plug-in, such as the ActiveX plug-in used at my institution, is inaccurate. Dr. Grizzard states that installing, configuring, and maintaining client software on hundreds of physicians' computers across an enterprise system is very expensive (see Grizzard Decl. ¶18). However, most hospitals have enterprise IT systems that greatly facilitate automated deployment of software onto all their computers, so that all software on each computer is always up-to-date and all security updates are installed as soon as they are released. This is how my hospital maintains its enterprise computers. An enterprise IT system, such as the system my hospital uses, greatly reduces the amount of time and money required to maintain client software on hospital computers.

62. Similarly, many of the conveniences that Heart IT suggests are only achievable with "zero-download" viewers are easily achievable using viewers that may require some additional download. Viewers requiring some download can also be easily integrated with an EHR system. If a download is required, there is not necessarily a need for a physician or end user to install and configure image viewing software. Rather, a download or installation may occur in the background without any action by the user, and it is often required only once. For example, the non-"zero-footprint" GE WebPACS viewer at my hospital uses a download that occurs subtly in the background without user involvement. Further, even

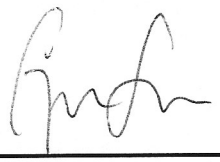
viewers requiring some download can function on many platforms and most often do not require user training as they are designed to be user-friendly and non-intrusive.

63. I further believe that Heart IT overstates the purported advantage its product will have in the market as a result of EHR incentive funding and Meaningful Use requirements. Many of the existing viewers in the market are now being certified for Meaningful Use. Therefore, for hospitals which have already purchased a viewer and have already deployed the viewer on their enterprise desktops, once the viewer becomes certified, a hospital can simply satisfy Meaningful Use requirements by integrating that existing viewer with its EHR, *even if the viewer is not* "*zero-footprint*." For example at my hospital, we have already successfully integrated our EHR with our non-"zero-footprint" GE WebPACS viewer. It was a straightforward configuration process and did not require an additional purchase of a "zero-download" viewer product. In other words, for most of the hospitals which already have an existing viewer, there would be no additional purchase to meet Meaningful Use requirements. There would also be no installation for these physicians since this existing viewer software had already been automatically installed and updated. In other words, EHR integration with the viewer would likely be completely seamless and without additional purchases for the large majority of hospitals in the U.S. who already have these PACS viewers.

64. There are several important factors when deciding which PACS system including an image viewer to purchase for a hospital. Several of the most important considerations include the reputation of the product and company, quality and terms of the service contract, and the ability for the PACS system to integrate with other existing information systems in the department and throughout the hospital. Having a "zero-download" viewer is a nice feature, but is not, in most scenarios, among the most important ones, in part because deployment of non-"zero-download" viewers to enterprise computers is largely a non-issue today because of software tools that can automate these installations and updates, which are available to most hospital IT departments. The "zero-footprint" aspect of a viewer is thus typically not a primary consideration in a hospital's decision-making process.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on January 22, 2013.



George Shih, M.D., M.S.